

§ 514.201

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in his appearance.

[40 FR 13825, Mar. 27, 1975, as amended at 43 FR 1941, Jan. 13, 1978]

§ 514.201 Procedures for hearings.

Hearings relating to new animal drugs under section 512(d) and (e) of the act shall be governed by part 12 of this chapter.

[64 FR 63204, Nov. 19, 1999]

Subparts D–E [Reserved]

Subpart F—Judicial Review

§ 514.235 Judicial review.

(a) The transcript and record shall be certified by the Commissioner. In any case in which the Commissioner enters an order without a hearing pursuant to § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

(b) Judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, may be sought by a manufacturer or distributor of an identical, related, or similar drug product, as defined in § 310.6 of this chapter, in a United States court of appeals pursuant to section 505(h) of the act.

[42 FR 4717, Jan. 25, 1977]

PART 515—MEDICATED FEED MILL LICENSE

Subpart A—Applications

Sec.

515.10 Medicated feed mill license applications.

515.11 Supplemental medicated feed mill license applications.

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Subpart B—Administrative Actions on Licenses

515.20 Approval of medicated feed mill license applications.

515.21 Refusal to approve a medicated feed mill license application.

515.22 Suspension and/or revocation of approval of a medicated feed mill license.

515.23 Voluntary revocation of medicated feed mill license.

515.24 Notice of revocation of a medicated feed mill license.

515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.

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Subpart C—Hearing Procedures

515.30 Contents of notice of opportunity for a hearing.

515.31 Procedures for hearings.

Subpart D—Judicial Review

515.40 Judicial review.

AUTHORITY: 21 U.S.C. 360b, 371.

SOURCE: 64 FR 63204, Nov. 19, 1999 unless otherwise noted.

Subpart A—Applications

§ 515.10 Medicated feed mill license applications.

(a) Medicated feed mill license applications (Forms FDA 3448) may be obtained from the Public Health Service, Consolidated Forms and Publications Distribution Center, Washington Commerce Center, 3222 Hubbard Rd., Landover, MD 20785, or electronically from the Center for Veterinary Medicine home page at “<http://www.fda.gov/cvm>”.

(b) A completed medicated feed mill license must contain the following information:

(1) The full business name and address of the facility at which the manufacturing is to take place.

(2) The facility's FDA registration number as required by section 510 of the Federal Food, Drug, and Cosmetic Act (the act).

(3) The name, title, and signature of the responsible individual or individuals for that facility.

(4) A certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in